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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Garibaldi et al.

Serial No.: 09/200,055

Filed: November 25, 1998

For: METHOD OF AND APPARATUS FOR NAVIGATING MEDICAL DEVICES IN BODY LUMENS BY A GUIDE WIRE WITH A MAGNETIC TIP

Examiner: Michael M. Thompson

Group Art Unit: 3763

Commissioner for Patents
Washington, D.C. 20321

APPLICANTS' BRIEF ON APPEAL

Pursuant to 37 C.F.R. § 1.192, Applicants submit their Brief on Appeal, as follows:

Real Party in Interest (37 C.F.R. § 1.192 (c)(I))

The real party in interest in this appeal is Stereotaxis, Inc., a Delaware corporation, having a place of business at 4041 Forest Park Avenue, St. Louis, MO 63108, by virtue of an assignment recorded November 25, 1998 at Reel 9615, Frame 0059.

Related Appeals and Interferences (37 C.F.R. §1.192(c)(2))

There are no other appeals or interferences known to Applicants, or to Applicants' legal representatives or assignees, which will directly affect, or would be directly affected by, or have a bearing on, the Board's decision in this appeal.

Status of the Claims (37 C.F.R. §1.192(c)(3))

Applicants have cancelled claims 1, 2, 5-8, 11-14, 17, 18, 20-25, 28, 29, 31-33, and 38-40, without prejudice. Claims 3, 4, 9, 10, 15, 16, 19, 26, 27, 30, 34-37, 41 and 42 remain pending in the application and were finally rejected in the Office Action of March 22, 2002.

Applicants respectfully submit that claims 4 and 10 may not be in proper dependent form. Applicants therefore withdraw claims 4 and 10 without prejudice, with the intention to reclaim the subject matter of claims 4 and 10 in this application or in a subsequent application. Accordingly, claims 3, 9, 15, 16, 19, 26, 27, 30, 34-37, 41 and 42 are the subject of this appeal.

Status of Amendments (37 C.F.R. §1.192(c)(4))

No amendments were filed after the final rejection of March 22, 2002.

Summary of Invention (37 C.F.R. §1.192(c)(5))

Applicants' invention relates to a magnetically controllable guide wire (402) for guiding medical devices. The guide wire can be used to guide a catheter (404) within body lumens such as blood vessels, the gastrointestinal tract, the trachea, and the urinary tract. The guide wire and medical device can be navigated within the lumen by applying a magnetic field, to the magnetic distal end of the guide wire (402). The guide wire includes a highly flexible wire (406) that can be manipulated at its proximal end by the operating physician, yet can also be advanced by the magnetic field applied to the distal end (page 18, lines 2-5).

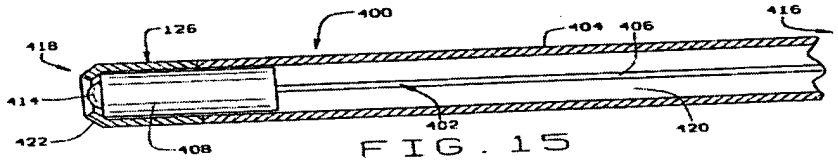


FIG. 15

A view of a guide wire and catheter combination. (Fig. 15 from Application Serial No. 09/200,055)

The claimed invention relates to two alternative constructions of the guide wire. According to one claimed construction, a series of magnets (166) are spaced apart from one another on the distal end portion (168) of the guide wire (160) (page 13, lines 1-4).

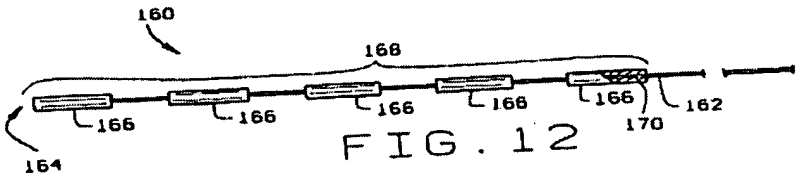


FIG. 12

A view of an alternative construction of the guide wire. (Fig. 12 from Application Serial No. 09/200,055)

When a magnetic field is applied, the magnets (166) cause the distal end portion of the guide wire to assume a particular shape dictated by the field.

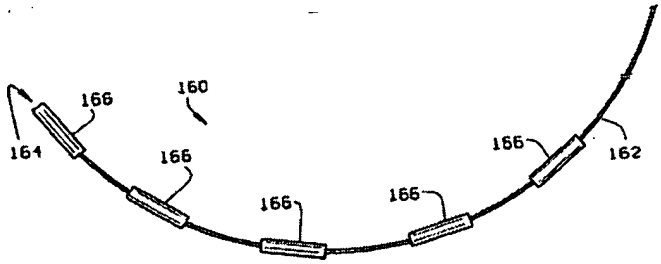


FIG. 12A

A view of the distal section of the guide wire in a magnetic field. (Fig. 12a from Application Serial No. 09/200,055)

In contrast to prior magnetically controlled guide wires, the present guide wire can be made to conform to the shape of a body lumen (Fig. 12a; page 13, lines 18-25). A magnetic pulling force can be used to hold the guide wire and catheter to the wall of the lumen (page 13, lines 25-29). Thus a physician is able to apply the distal end portion, not just the distal tip, of the guide wire and catheter against the lumen wall. The size and spacing of the magnets (166) can be varied to allow the guide wire to be

shaped, for example, to the wall of a patient's heart. The spaces between the magnets, moreover, do not have to be equal. This embodiment is particularly useful for guiding an electrophysiology catheter, by applying magnetic fields to pull or shape the guide wire to a patient's heart wall (page 13, lines 5-17). The guide wire (160) can be advanced by pulling with a magnetic force on the magnets (166), or the proximal end can be manually pushed (page 13, lines 35-27).

According to another claimed construction, the distal end portion (186) of the guide wire (180) is made from a flexible magnetic material (page 14, lines 1-3). The distal end portion can be made of a flexible, permeable magnetic material such as a steel or magnetic stainless steel wire or braid (page 14, lines 4-9).

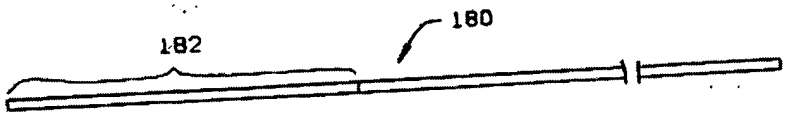


FIG. 13

A view of an alternate construction of the guide wire. (Fig. 13 from Application Serial No. 09/200,055)

When a magnetic field is applied, the distal end portion (186) of the guide wire (180) assumes a particular orientation dictated by the field.

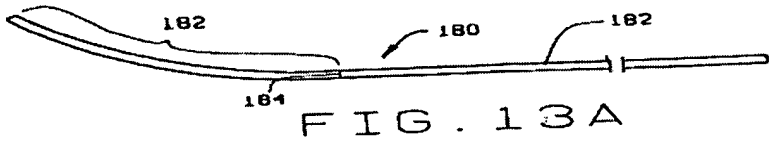


FIG. 13A

A view of the distal section of the guide wire in a magnetic field. (Fig. 13a from Application Serial No. 09/200,055)

The magnetic field can be controlled to orient, shape and also selectively stiffen the distal portion (186) of the guide wire, to facilitate navigation though the body lumen. To advance the guide wire (180), a physician can apply magnetic force to the distal end portion and/or can push the proximal end of the guide wire. In contrast, however, to prior mechanically controlled guide wires, the wire (182) of the guide wire needs only enough stiffness to overcome static friction when the proximal end of the guide wire (180) is pushed. This high degree of flexibility is possible because the magnetic field applied to the distal tip can provide sufficient stiffness to allow the guide wire to be navigated (page 14, lines 10-24).

Applicants' guide wire can be used to navigate a device for retrieving objects such as stents and stones from a patient. In contrast to prior guide wires, the present guide wire has such a high degree of articulation at the distal tip that it can provide the control needed to capture and recover such objects (page 18, lines 25-32).

Issues (37 C.F.R. §1.192(c)(6))

Are the apparatus set forth in claims 3, 9, 26, 30, and 42 and the methods set forth in claims 15, 16, 19, 34-37, and 41 anticipated under 35 U.S.C. §102(b) by Anderson, U.S. Patent No. 4,244,362?

Would the apparatus set forth in claims 3, 9, 26, 30 and 42 and the methods set forth in claims 15, 16, 19, 34-37, and 41 have been obvious under 35 U.S.C. §103(a) from Anderson, U.S. Patent No. 4,244,362?

Would the apparatus set forth in claim 27 have been obvious to a person of ordinary skill in the art under 35 U.S.C. §103(a) from Anderson, U.S. Patent No. 4,244,362?

Are the apparatus set forth in claims 3, 9, 26, 27, 30, and 42 and the methods set forth in claims 15, 16, 19, 34-37, and 41 unpatentable for obviousness-type double patenting over claims 1-18 of Werp et al., U.S. Patent No. 5,931,818?

Grouping of Claims (37 C.F.R. §1.192(c)(7))

As shall be discussed below, claims 3, 9, 16 and 41 each stand alone, and each of claims 34 through 37 stand alone. Claims 15 and 19 stand together. Claims 26 and 30 stand together. Claims 27 and 42 stand together.

Argument (37 C.F.R. §1.192(c)(8))

THE APPARATUS SET FORTH IN CLAIMS 3, 9, 26, 30, AND 42, AND THE METHODS SET FORTH IN CLAIMS 15, 16, 19, 34-37 AND 41 ARE NOT ANTICIPATED UNDER 35 U.S.C. §102(b) BY ANDERSON, U.S. PATENT NO. 4,244,362.

Claims 3, 9, 15 (and claim 19, which depends from claim 15), and 26 (and claim 30, which depends from claim 26) describe a guide wire in which a flexible magnetic material forms a distal end section of the guide wire. A guide wire having an end section of flexible magnetic material is significantly different from the stylet shown in Anderson, U.S. Patent No. 4,244,362. Anderson describes a stylet for inserting an endotracheal tube. The stylet body is a coiled non-magnetic spring, the distal end of which encases a row of magnets (column 6, lines 5-10; line 55). The magnets are strongly attracted to one another and function together as a single magnet (column 7, lines 28-30), always exhibiting the same polarity so as to be consistently attracted toward a larger magnet positioned on the throat of a patient. The magnets can be separated only partially from one another when attracted by the larger magnet.

Applicants respectfully submit that the magnetic characteristics exhibited by a flexible magnetic material are substantially different from those exhibited by the magnets of Anderson. Applicants further submit that a flexible magnetic material behaves differently from any other "magnetic means" that might be contemplated for use in the Anderson stylet. The common polar alignment and strong mutual attraction of the row of magnets in Anderson preclude them from being magnetically attracted in any direction other than in single-file behind the larger magnet (Anderson, reference number 63) toward the larger magnet on the patient's throat. This single-file attraction is necessary to ensure that the stylet tip enters the trachea. To allow the stylet distal end

portion to be moved laterally toward the trachea would prevent the tip from entering the trachea. Thus Anderson teaches away from magnetically attracting the distal portion of the stylet so as to cause lateral movement of the distal portion.

In contrast, the flexible magnetic material of Applicants' guide wire behaves in ways utterly unanticipated by the row of magnets of Anderson. A flexible stainless steel braid, for example, can be selectively magnetized in different directions, depending on the direction and strength of the applied magnetic fields. The distal portion of Applicants' guide wire thus can be moved in any direction. Such permeable magnetic materials are easier to pull than permanent magnets under application of a magnetic field (page 6, lines 32-36). The distal end of Applicants' guide wire is so highly flexible that it enables the capture and recovery of objects such as stents and stones from a patient. (page 18, lines 25-32).

The Examiner takes the position that the magnetic material taught by Anderson is inherently flexible with regard to other materials. He supports this position by observing that the coiled spring is preferably made of metal. However, the spring, the only flexible component of the stylet, is expressly described as non-magnetic (column 6, lines 5-10; line 55). Furthermore, it is clear that the individual magnets are not inherently flexible.

It is not inherent in Anderson to use flexible magnetic materials such as steel, stainless steel wire, and/or stainless steel braid. To the contrary, Anderson teaches using a magnetic means that is constrained to act as a single magnet having a magnetic field oriented in a single direction. Anderson teaches away from using a metallic material in the stylet distal end, because the use of only a metallic material would reduce the ability to direct the stylet end into the trachea (column 7, lines 31-41).

Additionally, claim 26 (and claim 30 depending from claim 26) recites a guide wire that extends into the lumen of a medical device with the magnetic distal tip of the guide wire in the distal end of the lumen in the medical device. This arrangement is not anticipated by Anderson. Anderson not only describes, but requires, a stylet tip that extends through and past the lumen of an endotracheal tube (column 4, lines 20-21).

The apparatus of claim 27 (and claim 42 which depends from claim 27) and the methods of claim 16 (and claim 41 depending from claim 16), and claim 34 (and claims

35-37 depending from claim 34) describe a magnetic distal tip having a plurality of magnets on the distal end section of the guide wire in spaced apart relation. A guide wire having a plurality of spaced-apart magnets is significantly different from the stylet shown in Anderson, U.S. Patent No. 4,244,362. The magnets taught by Anderson are strongly attracted to one another and function together as a single magnet (column 7, lines 28-30). They may separate only partially from one another when attracted by a larger magnet positioned on the throat of a patient.

In contrast, the magnets of Applicants' guide wire are spaced apart from one another. Their relative spacing and relative size allow the guide wire distal end portion to conform to the shape of the applied magnetic field lines to assume a specific shape, e.g. to conform to the shape of a body lumen (Fig. 12a; page 13, lines 18-25). They can be controlled to take the shape of, and hold a medical device against, the wall of a body lumen. Unlike the magnets of Anderson, Applicants' spaced-apart magnets do not necessarily attract one another, regardless of whether or not an external magnetic field is being applied to them (Figs. 12 and 12a). Using spaced-apart magnets is contrary to the teaching of Anderson, which requires magnetically attracting the tip of the stylet so as to compel the rest of the stylet to follow longitudinally behind the tip toward the trachea of a patient. The magnets in Applicants' apparatus are spaced so that each shapes the adjacent regions of the guide wire; the magnets in Anderson function as a unit, and thus are not "spaced" as required by Applicants' claims.

Additionally, claim 34 and claims 35-37, which depend from claim 34, recite inserting a guide wire into the lumen of a medical device until the magnetic tip of the guide wire is substantially adjacent the distal end of the medical device. This arrangement is not anticipated by Anderson. Anderson not only describes, but requires, a stylet tip that extends through and past the lumen of an endotracheal tube (column 4, lines 20-21).

A guide wire with flexible magnetic material as claimed in claims 3, 9, 15, 19, 26 and 30 is not shown, described nor inherent in Anderson. A plurality of spaced-apart magnets claimed in claims 16, 34-37, 41 and 42 are not shown or described in Anderson. Additionally, claims 26, 30, 34-37 and 42 require that a magnetic tip is

disposed in the lumen of the medical device, contrary to the teaching of Anderson. The rejection of claims 3, 9, 15, 16, 19, 26, 30, 34-37, 41 and 42 under 35 U.S.C. §102(b) should be reversed.

THE APPARATUS SET FORTH IN CLAIMS 3, 9, 26, 30 AND 42 AND THE METHODS SET FORTH IN CLAIMS 15, 16, 19, 34-37, AND 41 WOULD NOT HAVE BEEN OBVIOUS UNDER 35 U.S.C. §103(a) IN VIEW OF ANDERSON, U.S. PATENT NO. 4,244,362.

Applicants' spaced-apart magnets are not obvious in view of the row of magnets or other "magnetic means" that may be taught by Anderson and the method of claims 35, 36, 16, 34. Although it may be well known in the art that one magnet may replace many magnets, or vice versa, such can be the case only where the many magnets and the one magnet possess equivalent magnetic characteristics. Applicants' plurality of spaced-apart magnets have magnetic characteristics quite different from those of the magnets taught by Anderson. For example, because Applicants' magnets are spaced apart, whatever mutual attractions they may exhibit are significantly lower than those of the closely packed magnets taught by Anderson. As another example, the spacing of Applicants' magnets along the distal portion of the guide wire allow the magnets to be moved relative to one another such that their magnetic alignments do not have to remain constant, let alone parallel. Thus, although the Examiner's visualization of a permanent magnet as a large number of particles having parallel magnetic alignment might be supportable, it is irrelevant to Applicants' plurality of spaced apart magnets.

It is clear that Applicant's guide wire does not constitute a duplication of the essential working parts of the stylet of Anderson. As previously discussed, it is essential in Anderson that the "first magnetic means" act as a single magnet, so that the distal tip, and only the tip, of the stylet is directed toward the trachea by the "second magnetic means", *i.e.* the larger magnet positioned on the trachea. The polar alignment and mutual attraction of the spring-enclosed magnets preclude them from being magnetically attracted in any direction other than in single-file toward the "second magnetic means". Additionally, the endotracheal tube must be freely movable over the stylet and the "first magnetic means", so as to permit free flow of air along the lumen of

the tube. Allowing lateral movement of the magnets could allow the magnets to block the lumen of the endotracheal tube as the stylet is withdrawn.

In contrast to the "first magnetic means" of Anderson, each claimed construction of the magnetic distal end section of Applicant's guide wire is configured to move in a plurality of directions and to take a plurality of shapes, as determined by the applied magnet fields. Such versatility is not anticipated by Anderson.

Claims 35 and 36 depend from claim 34. Applicants submit that claim 34 is patentable for the reasons stated above. Dependent claim 35 requires a magnetic distal tip comprising a plurality of magnets on the distal end section of the guide wire in spaced apart relation, wherein the magnetic tip comprises a permeable magnetic material. Dependent claim 36 requires a magnetic distal tip comprising a plurality of magnets on the distal end section of the guide wire in spaced apart relation, wherein the magnetic tip comprises a permanent magnetic material.

Applicants respectfully submit that permeable magnetic material and permanent magnets as incorporated into Applicants' guide wire have different useful characteristics and are properly claimed dependent on claim 34. For example, permanent magnets are easier to orient under the application of a magnetic field, while permeable magnetic material is easier to pull under the application of a magnetic field (page 6, lines 32-36). Accordingly, Applicants submit that dependent claims 35 and 36 are patentable.

THE COMBINATION SET FORTH IN CLAIM 27 WOULD NOT HAVE BEEN OBVIOUS UNDER 35 U.S.C. §103(a) IN VIEW OF ANDERSON, U.S. PATENT NO. 4,244,362.

Claim 27 is directed to a guide wire and medical device combination in which the magnetic distal tip of the guide wire comprises a plurality of magnets on the distal end section of the guide wire in spaced apart relation, the guide wire extending into the lumen of the medical device with the magnetic distal tip in the distal end of the lumen in the medical device. Applicants submit that the combination set forth in claim 27 would not have been obvious in view of Anderson, U.S. Patent No. 4,244,362.

As discussed above, Anderson requires that the row of magnets in the stylet tip be strongly attracted to one another and act as a single magnet. In contrast, Applicants' plurality of magnets on the distal end section of the guide wire are in spaced apart

relation and are not necessarily attracted to one another. Thus the combination of claim 27 does not merely duplicate the essential working parts of the device of Anderson.

Additionally, the Examiner states that it would have been obvious to make or use the device of Anderson with multiple magnetic means disposed radially about the distal end of the catheter. It is neither required nor anticipated by Anderson, however, that a plurality of magnets be radially arranged about the distal end of the catheter by an applied magnetic field. To the contrary, Anderson teaches against the attraction of "first magnetic means" by "second magnetic means" while the "first magnetic means" is inside a medical device.

Claim 27 and thus claim 42, which depends from claim 27, recite a guide wire that extends into the lumen of a medical device with the magnetic distal tip of the guide wire in the distal end of the lumen in the medical device. This arrangement is not anticipated by Anderson. Anderson not only describes, but requires, a stylet tip that extends through and past the lumen of an endotracheal tube. The apparatus of claims 27 and 42 are not anticipated by, nor obvious from, Anderson.

THE APPARATUS SET FORTH IN CLAIMS 3, 9, 26, 27, 30 AND 42 AND THE METHODS SET FORTH IN CLAIMS 15, 16, 19, 34-37 AND 41 ARE NOT UNPATENTABLE UNDER OBVIOUSNESS-TYPE DOUBLE PATENTING OVER CLAIMS 1-18 OF WERP ET AL., U.S. PATENT NO. 5,931,818.

Applicants' claims 3, 9, 15, 16, 19, 26, 27, 30, 34-37, 41 and 42 are patentably distinct and not merely obvious variations of the invention set forth in claims 1-18 of Werp et al., U.S. Patent No. 5,931,818.

Applicants' claims 3, 9, 15 (and claim 19, depending from claim 15), and 26 (and claim 30, depending from claim 26) require a guide wire in which a flexible magnetic material forms the distal end section of the guide wire. A guide wire having an end section of flexible magnetic material is significantly different from the magnet and attached guide wire described in Werp et al. It is neither obvious nor suggested in view of Werp et al. to use a flexible magnetic material for navigating a medical device. Further, it is neither obvious nor suggested in view of Werp et al. to use a guide wire that extends beyond the distal end of the medical device as recited in Applicants' claims

9 and 15 (and claim 19 depending from claim 15). Werp et al. do not teach or suggest advancing the medical device over the guide wire as recited in Applicants' claims 15 and 19.

Claims 16 (and claim 41 depending from claim 16), 27 (and claim 42 depending from claim 27), and claim 34 (and claims 35-37 depending from claim 34) require a magnetic distal tip having a plurality of magnets on the distal end section of the guide wire in spaced apart relation. A guide wire having a plurality of spaced-apart magnets is significantly different from the magnet and attached guide wire described in Werp et al. Werp et al. describe a guide wire and magnet for navigating through body tissue. It is neither obvious nor suggested in view of Werp et al. to use a guide wire having plurality of spaced-apart magnets for navigating through a body lumen. Further, Werp et al. do not suggest allowing the guide wire to assume a shape under control of the magnetic field, as claimed in Applicants' claim 16 (and claim 41 depending from claim 16). It is neither obvious nor suggested in view of Werp et al. to use a guide wire extending beyond the distal end of the medical device as recited in Applicants' claim 16 (and claim 41 depending from claim 16). Werp et al. do not teach or suggest advancing the medical device over the guide wire as recited in Applicants' claims.

For at least these reasons, Applicants' claims should not be rejected under obviousness-type double patenting over claims 1-18 of Werp et al.

Conclusion

Claims 3, 9, 15, 19, 26 and 30 require a flexible magnetic material, *i.e.*, one that flexes in response to the applied magnetic field. This is not shown or suggested in Anderson, and thus Anderson cannot anticipate or make obvious the invention of these claims. This claimed structure allows the distal end of the device to assume the shape of the local magnetic field direction and/or to selectively stiffen to facilitate navigation.

Claims 16, 34-37, 41 and 42 require a plurality of spaced-apart magnets. This is not shown or suggested in Anderson, where the plurality of magnets are not spaced apart, but grouped together to function as a unit. This allows the distal end of the device to take on the shape of the applied magnetic field, each spaced magnet shaping the adjacent portion of the guidewire, rather than the magnets responding as a single unit

as in Anderson. Additionally, claims 26, 30, 34-37 and 42 require a magnetic tip that does not extend past the lumen of the medical device, contrary to the teaching of Anderson. Therefore Applicants' claims 3, 9, 15, 16, 19, 26, 30, 34-37, 41 and 42 are not anticipated under 35 U.S.C. §102(b) by Anderson, U.S. Patent No. 4,244,362.

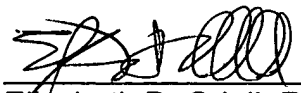
The distal end section of Applicants' guide wire recited in claims 3, 9, 15, 16, 19, 26, 30, 34-37, 41 and 42 is configured to move in a plurality of directions and to take a plurality of shapes. The magnetic distal end portion of Applicants' guide wire exhibits magnetic characteristics substantially different from those of the magnets taught by Anderson, U.S. Patent No. 4,244,362. Thus Applicants' guide wire does not constitute a duplication of the essential working parts of the stylet of Anderson, U.S. Patent No. 4,244,362. Therefore Applicants' methods and apparatus set forth in claims 3, 9, 15, 16, 19, 26, 30, 34-37, 41 and 42 are not obvious under 35 U.S.C. §103(a) over Anderson, U.S. Patent No. 4,244,362.

Applicants' plurality of magnets on the distal end section of the guide wire are in spaced apart relation and are not necessarily attracted to one another. Thus the combination of claim 27 does not merely duplicate the essential working parts of the device of Anderson. Thus the combination set forth in claim 27 is not obvious under 35 U.S.C. §103(a) over Anderson, U.S. Patent No. 4,244,362.

Werp et al. do not teach or suggest flexible magnetic material required in claims 3, 9, 15, 19, 26 and 30 or a plurality of magnets in spaced apart relation at the distal end portion of a guide wire required in claims 16, 34-37, 41 and 42. Further, it is neither obvious nor suggested in view of Werp et al. to use a guide wire extending beyond the distal end of the medical device as recited in Applicants' claims 9, 15 (and claim 19 depending from claim 15) and 16 (and claim 41 depending from claim 16). Thus Applicants' claims 3, 9, 15, 16, 19, 26, 27, 30, 34-37, 41 and 42 are patentably distinct and not merely obvious variations of claims 1-18 of Werp et al., U.S. Patent No. 5,931,818. Therefore Applicants' claims 3, 9, 15, 16, 19, 26, 27, 30, 34-37, 41 and 42 are not unpatentable under obviousness-type double patenting over claims 1-18 of Werp et al., U.S. Patent No. 5,931,818.

The rejections of claims 3, 9, 15, 16, 19, 26, 27, 30, 34-37, 41 and 42 therefore should be reversed.

Respectfully submitted,



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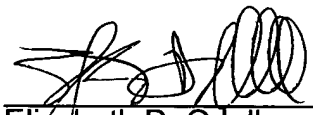
CERTIFICATE OF MAILING

I certify that on August 26, 2002, APPLICANTS' BRIEF ON APPEAL (in triplicate) was sent by U.S. Postal Service Express Mail to the U.S. Patent and Trademark Office, address to Commissioner for Patents, U.S. Patent and Trademark Office, Washington, D.C. 20231.



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APPENDIX
(CLAIMS ON APPEAL)

3. A wire for use in navigating a medical device through a body lumen to a particular location, the guide wire having a proximal end and a distal end, and a magnet on the distal end, the guide wire being sufficiently flexible adjacent the magnet to allow the wire to flex in response to a magnetic field applied to the magnet, yet the wire being sufficiently stiff to allow the wire to be advanced through the body lumen;

wherein the magnet on the distal end comprises a flexible magnetic material forming a distal end section of the guide wire.

9. In combination with a medical device having a proximal end, a distal end, and a lumen therebetween, a guide wire having a proximal end, a distal end, and a magnet on the distal end, the guide wire extending through the lumen of the medical device, with the distal end of the guide wire extending beyond the distal end of the medical device;

wherein the magnet on the distal end comprises a flexible magnetic material forming a distal end section of the guide wire.

15. A method of navigating a medical device through a body lumen to a desired location within the body, the method comprising:

providing a medical device having a lumen therethrough, the lumen having a proximal end and a distal end;

inserting a guide wire having a proximal end and a magnetic distal tip, the distal tip of the guide wire being made from a flexible magnetic material, through the lumen of the device until at least a portion of the magnetic distal tip extends distally beyond the distal end of the lumen in the medical device;

inserting the medical device and the guide wire into a lumen in the body;

navigating the medical device through the lumen in the body by applying a magnetic field to orient the magnetic tip in the desired direction of travel;

advancing the guide wire in the direction in which the magnetic tip is oriented; and

advancing the medical device over the guide wire;

wherein the magnetic tip of the guide wire comprises a distal section of the guide wire being made from a flexible magnetic material.

16. A method of navigating a medical device through a body lumen to a desired location within the body, the method comprising:

providing a medical device having a lumen therethrough, the lumen having a proximal end and a distal end;

inserting a guide wire, having proximal end and a magnetic distal tip comprising a plurality of magnets secured on the distal end section of the guide wire in spaced apart relation allowing the guide wire to assume a shape under control of the magnetic field, through the lumen of the device until at least a portion of the magnetic distal tip extends distally beyond the distal end of the lumen in the medical device;

inserting the medical device and guide wire into a lumen in the body;

navigating the medical device through the lumen in the body by applying a magnetic field to shape the magnetic distal tip in the desired configuration to the orient the magnetic tip in the desired direction of travel;

advancing the guide wire in the direction in which the magnetic tip is oriented; and

advancing the medical device over the guide wire.

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19. The method according to claim 15, wherein the step of navigating the medical device comprises successively incrementally advancing the guide wire and the medical device.

26. In combination with a guide wire having a proximal end, a distal end, and a magnetic distal tip, a medical device having a proximal end, a distal end, and a lumen extending substantially to the distal end of the device, the guide wire extending into the

lumen of the medical device with the magnetic distal tip in the distal end of the lumen in the medical device;

wherein a distal end portion of the guide wire is sufficiently flexible to allow the magnetic tip to move in response to an applied magnetic field, but a proximal section of the guide wire is sufficiently stiff to advance the medical device through a lumen in the body; and

wherein the magnetic distal tip comprises a flexible magnetic material forming a distal end section of the guide wire.

27. In combination with a guide wire having a proximal end, a distal end, and a magnetic distal tip, the magnetic distal tip comprises a plurality of magnets on the distal end section of the guide wire in spaced apart relation, the portion of the guide wire adjacent the distal end being sufficiently flexible to allow the magnetic tip to move in response to an applied magnetic field, but the proximal section of the guide wire being sufficiently stiff to advance a medical device through a lumen in the body,

a medical device having proximal end, a distal end, and a lumen extending substantially to the distal end of the device, the guide wire extending into the lumen of the medical device with the magnetic distal tip in the distal end of the lumen in the medical device.

30. The combination according to claim 26 wherein the lumen of the medical device has a stricture therein for engaging the guide wire and retaining the guide wire in the lumen of the medical device.

34. A method of navigating a medical device through a body lumen to a desired location within the body, the method comprising:

providing a medical device having a proximal end, a distal end, and a lumen extending to substantially the distal end of the medical device;

inserting a guide wire having a proximal end and a magnetic distal tip into the lumen until the magnetic tip is substantially adjacent the distal end of the medical

device, the magnetic tip of the guide wire comprises a plurality of magnets secured on the distal end section of the guide wire in spaced apart relation;

inserting the medical device and the guide wire into a lumen in the body;

navigating the medical device through the lumen in the body by applying a magnetic field to orient the magnetic tip inside the lumen of the medical device so that the distal end of the medical device is oriented in the desired direction of travel; and

advancing the guide wire and medical device in the direction in which the distal end of the medical device is oriented.

35. The method according to claim 34 wherein the magnetic tip comprises a permeable magnetic material.

36. The method according to claim 34 wherein the magnetic tip comprises a permanent magnetic material.

37. The method according to claim 34, wherein the step of navigating the medical device comprises successively orienting and advancing the guide wire and medical device.

41. The method according to claim 16, wherein the step of navigating the medical device comprises successively incrementally advancing the guide wire and the medical device.

42. The combination according to claim 27 wherein the lumen of the medical device has a stricture therein for engaging the guide wire and retaining the guide wire in the lumen of the medical device.